

### **REMARKS**

The July 31, 2008 final Office Action addresses claims 1-3, 5, 6, 9, 10, 15-20, 22-24, 26-30, and 48-56, in which the Examiner rejects claims 1-3, 5, 6, 9, 10, 15-17, 19-20, 22-24, 26-30, and 48-56 pursuant to 35 U.S.C. §§ 112 and/or 103. Independent claim 18 is allowed.

Applicants hereby amend claims 1, 5, 9, 19, 23-24, 26, 28, 30, and 50-53, and cancel claims 2, 3, 10, 20, 22, and 27. Applicants also add new claims 57-104. In view of the following amendments and remarks, Applicants respectfully request reconsideration and allowance of claims 1, 5, 6, 9, 15-19, 23-24, 26, 28-30, and 48-104.

#### ***Examiner Interview***

Applicants would like to thank the Examiner for the meeting with Applicants' attorneys Reza Mollaaghababa and Thomas Engellenner on December 3, 2008 at the United States Patent and Trademark Office. During the interview, the pending claims and rejection were discussed. Applicants agreed to amend the claims to overcome certain rejections pursuant to 35 U.S.C. § 112. Applicants also discussed possible claim amendments with regards to rejections pursuant to 35 U.S.C. § 103. No agreement was reached.

#### ***Claim Amendments***

Applicants amend claims 1, 5, 9, 19, 23-24, 26, 28, 30, and 50-53, and add new claims 57-104. Support for these amendments and new claims can be found throughout the specification as filed as described in detail below.

Applications amend independent claim 1 to recite:

A method *for providing a dermatological or cosmetic treatment*, comprising:  
    inserting at least a portion of a phototherapy applicator into an oral cavity; and  
    irradiating an area of tissue in the oral cavity *in a direction of facial tissue* with radiation from the phototherapy applicator *so as to deposit a dose of radiation below an area of facial skin*, and having at least one wavelength component corresponding to the absorption spectrum of a light acceptor in the oral cavity or in *facial tissue*,

wherein the area of tissue is irradiated so as to *treat a dermatological or cosmetic condition in said area of the facial tissue.*

Support for these amendments is found throughout the specification as filed, for example, at paragraphs [0016], [0069], [0080], [0109], and [0130]. No new matter is added.

Applicants amend dependent claim 5 to recite the light acceptor is located within *blood flowing in vasculature of at least one of the oral cavity and facial tissues* being irradiated. Support for this amendment is found throughout the specification as filed, for example, in original claim 20 and in paragraphs [0109], and [0139] – [0140]. No new matter is added.

Applicants amend dependent claim 9 to recite that the light acceptor can also include *hair follicles*. Support for this amendment can be found throughout the specification, for example, at paragraph [0141]. No new matter is added.

Applicants amend dependent claim 19 to recite that detecting diagnostic signals from said area of tissue can monitor *cosmetic or treatment results*. Support for this amendment is found throughout the specification as filed, for example, at paragraphs [0016], [0118], [0152], and [0155]. No new matter is added.

Applicants amend independent claim 53 to recite:

A method of biostimulation via an oral cavity, comprising  
irradiating at least a portion of tissue in an oral cavity with  
electromagnetic radiation having a power density *equal to or greater than about 1 W/cm<sup>2</sup>* and at least one wavelength corresponding to an  
absorption band of an *endogenous* photoreactive substance located in the  
portion of tissue;  
wherein the photoreactive substance absorbs sufficient  
electromagnetic radiation to cause the selected biostimulation effect.

Support for these amendments can be found throughout the specification as filed and at least in original claims 25 and 26, paragraphs [0018], [0070], [0105], [0109], [0111], [0120], [0126] – [0128], [0132] – [0133], [0136], [0146], [0154], and [0166]. No new matter is added.

New claim 57 depends from independent claim 1, and recites that the step of irradiating further comprises irradiating for a duration in a range of about 1 s to about one hour. Support for

this amendment can be found throughout the specification as filed, for example at paragraph [0166]. No new matter is added.

New claim 58 depends from claim 1, and recites that the method further comprises preferential deposition of radiation to the facial tissue. New claim 59 depends from claim 58, and recites that the preferential deposition of radiation comprises depositing the dose of radiation in the direction of the facial tissue. Support for these claims can be found throughout the specification as filed, for example, at paragraphs [0069], [0080], and [0130].

Applicants add new claim 60 which depends from claim 1, and finds support in at least original claim 11. New claims 61-65 depend from claim 1, and recite various ranges for power density (claims 61 and 62), energy flux (claims 63 and 64), and power (claim 65). Support for these new claims can be found throughout the specification as filed, for example, at paragraphs [0140], [0141], [0142], and [0166]. No new matter is added.

New claim 66 depends from claim 1, and recites that the step of irradiating further comprises irradiating the area of tissue with multiple, distinct wavelength bands. New claims 67 and 68 depend, directly or indirectly, from claim 66 and provide specific wavelength bands. Support for these claims can be found throughout the specification as filed, for example, at paragraphs [0086] and [0116]. No new matter is added.

New claim 69 depends from claim 1, and recites that the method further includes heating said area of tissue by applying radiation at another wavelength thereto. Claims 70-73 depend from claim 69, and provide various wavelength ranges and the use of first and second radiation sources (claim 72). Support for these claims can be found throughout the specification, for example at paragraph [0079] and in original claim 22. No new matter is added.

New claims 74 – 77 depend from independent claim 53, and support for these claims can be found at least in original claims 7, 8, 10, and 11, respectively. No new matter is added.

New independent claim 78 recites:

A biostimulation method, comprising:  
inserting at least a portion of a phototherapy applicator into an

oral cavity;

irradiating an area of tissue in the oral cavity with radiation from the phototherapy applicator, the radiation having multiple distinct wavelength bands corresponding to one or more absorption spectra of one or more light acceptors in the oral cavity or in tissue associated with the oral cavity, said one or more light acceptors absorbing at least one radiation wavelength in each of said bands;

wherein the area of tissue is irradiated concurrently with said multiple wavelength bands so as to provide a desired biostimulation.

Support for this claim can be found throughout the specification as filed, for example, at paragraphs [0086], [0087], and [0116].

New claim 79 depends from claim 78, and recites that the irradiation step includes at least one wavelength band which provides heating of the tissue by absorption in water or in blood. Support for this claim can be found at least at paragraph [0079]. Claims 80 and 82 each depend from claim 78, and recite various wavelength ranges. Support for these claims can be found through the specification, for example at paragraph [0079] and original claim 22. No new matter is added.

New claims 83 and 84 depend from claim 78, and recite various acceptors. Support for these claims can be found throughout the specification as filed, for example, at paragraphs [0111], [0120], [0130], [0141], and generally at paragraphs [0119] – [0150]. No new matter is added.

New claim 85 depends from claim 78, and recites that the irradiating step includes at least one wavelength band causing hyperthermia in the soft tissues of the oral cavity. Support for this claim can be found throughout the specification as filed, for example, at paragraphs [0121] – [0127], [0141] – [0143], and [0150]. No new matter is added.

New claim 86 depends from claim 78, and recites that the tissue comprises blood. New claim 87 depends from claim 78, and recites the irradiation step includes at least one wavelength band causing increased microcirculation in the soft tissues of the oral cavity and another wavelength band causing a therapeutic effect. Support for these claims can be found throughout the specification as filed, for example, in the Abstract and in paragraphs [0014], [0109]-[0110],

[0121]-[0128], [0132]-[0133], [0135]-[0136], [0139], [0141], and [0143]-[0145]. No new matter is added.

New claims 88 – 91 depend from claim 78, directly or indirectly, and correspond to original claims 7, 8, 10, and 11, respectively. Thus, no new matter is added. New claims 92 – 96 depend from claim 78, and recite various ranges for power density (claims 92 and 93), energy flux (claims 94 and 95), and power (claim 96). Support for these claims can be found throughout the specification as filed, for example, at paragraphs [0140], [0141], [0142], and [0166]. No new matter is added.

Applicants add new independent claim 97, reciting:

A method of treating a subject's blood, comprising:  
    exposing at least a portion of a subject's oral cavity to radiation  
    having wavelength components in a range of about 280 nm to about 1800  
    nm to irradiate blood flowing in vasculature of the oral cavity;  
    irradiating the oral cavity with said radiation during separate  
    treatment sessions such that a radiation power in a range of about 1 mW  
    to about 10 W is administered to the oral cavity during each treatment  
    session; and  
    irradiating the subject's oral cavity for a sufficiently long time so  
    as to expose substantially an entire volume of the subject's blood to said  
    radiation in one or more treatment sessions.

Support for this claim can be found in the originally filed claims, and throughout the specification as filed. For example, support for this claim can be found in original claims 20, 22, 25, and 27. No new matter is added.

Applicants amend pending claims 23, 24, and 26 to depend from new claim 97, and also amend the cited wavelength range of claims 23 and 24, and the cited power of claim 26. Support for these amendments can be found throughout the specification as filed, for example, at paragraphs [0131] and [0146] for claims 23 and 24, and at paragraph [0166] for claim 26. No new matter is added.

Applicants also amend claim 30 to depend from new claim 97, and also clarify the claim language. Applicants also amend pending claims 28, and 50-52 to depend from new independent claim 97. No new matter is added.

Applicants also add various new claims depending from new independent claim 97. New claims 98 – 102 depend from claim 97, and recite various ranges of power, energy flux, and treatment times. Support for these claims can be found throughout the specification, for example, at paragraph [0166].

New claim 103 depends from claim 97, and recites that the step of irradiating further comprises sufficiently irradiating to improve immunocompetence. New claim 104 depends from claim 97, and recites that the step of irradiating further comprises sufficiently irradiating to prevent bilirubinenima. Support for these claims can be found throughout the specification as filed, for example, at paragraph [0146] for claim 103, and at paragraph [0148] for claim 104. No new matter is added.

***Claim Rejections Pursuant to 35 U.S.C. § 112***

The Examiner rejects independent claim 1, and all claims depending therefrom, *i.e.*, claims 5, 6, 9, 15-17, 19, 48, and 49, pursuant to 35 U.S.C. § 112, *first paragraph*, as purportedly failing to comply with the written description requirement. More specifically, the Examiner argues that “[T]he specific power intensity of 0.35 W/cm<sup>2</sup> to 10 W/cm<sup>2</sup> is new matter not in the original disclosure.” Office Action, p. 3.

Applicants amend independent claim 1 to delete the limitation of a power intensity of 0.35 W/cm<sup>2</sup> to 10 W/cm<sup>2</sup>. Thus, the Examiner’s rejection of claim 1, as well as the rejection of claims 5, 6, 9, 15-17, 19, 48, and 49, are obviated.

The Examiner also rejects claim 52 pursuant to 35 U.S.C. § 112, *first paragraph*, because “[E]xposing an entire volume of blood in a single treatment is new matter. Prior disclosure allowed such exposure in more than a single treatment.” Office Action, p. 3. Applicants respectfully disagree for the following reasons.

The M.P.E.P. instructs:

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that

one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention.

M.P.E.P § 2163 (I).

The M.P.E.P. goes on to state:

In addition, early opinions suggest the Patent and Trademark Office was unwilling to find written descriptive support when the only description was found in the claims; however this viewpoint was rejected. See *In re Koller*, 613 F.2d 819, 204 USPQ 702 (CCPA 1980). . . . It is now well accepted that a satisfactory description may be in the claims or any other portion of the originally filed specification. These early opinions did not address the quality or specificity of particularity that was required in the specification, i.e., how much description is enough.

M.P.E.P § 2163 (I).

Original claim 27 recites the step of irradiating the subject's oral cavity for a sufficiently long time so as to expose substantially an entire volume of the subject's blood to said radiation *over one or more treatment cycles*. This teaching clearly provides one skilled in the art with written description for the limitation of claim 52, which recites one treatment cycle. Thus, Applicants respectfully request removal of this rejection.

### ***Claim Rejections Pursuant to 35 U.S.C. § 103***

The Examiner rejects claims 1-3, 5, 6, 8-10, 13, 15-17, 20, 22, 26-30 and 48-56 pursuant to 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,159,236 of Biel ("the Biel patent") in view of U.S. Patent Application Publication No. 2002/0183808 of Biel ("the Biel application").

### **Independent Claim 1 and Dependent Claims 5, 6, 9, 15-17, and 57-73**

As amended, independent claim 1 recites a method for providing a dermatological or cosmetic treatment which includes inserting at least a portion of a phototherapy applicator into an oral cavity, and irradiating an area of tissue in the oral cavity in a direction of facial tissue with radiation from the phototherapy applicator so as to deposit a dose of radiation below an area of facial skin. The method further recites that said radiation includes at least one wavelength component corresponding to the absorption spectrum of a light acceptor in the oral cavity or in

facial tissue wherein the area of tissue is irradiated so as to treat a dermatological or cosmetic condition in said area of the facial tissue.

The Examiner rejects claim 1 because “[T]he main manipulative steps claimed are inserting an applicator into an oral cavity and irradiating tissue in the oral cavity. A reference that provides such steps inherently would irradiate any endogenous acceptors as, by definition, they are present and having irradiated the acceptor the same result would occur.” Office Action, p. 2.

For a reference to inherently teach a claim, the M.P.E.P. instructs:

To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991).

M.P.E.P. § 2131.01 (III).

The Examiner provides the Biel patent as purportedly inherently disclosing the method of claim 1. Biel provides a medical device for photodynamic therapy (“PDT”). More specifically, the Biel device includes an expandable member and a light source for PDT treatment of the larynx or cheek so as to treat or detect pathogens of living tissue, including cancer or microbiological pathogens. See Biel, col. 1, lines 6-15.

Claim 1, as amended, recites a method for providing a dermatological or cosmetic treatment. In contrast, Biel teaches a method of treating cancer or some other disease. The Examiner contends that the Biel treatment would necessarily perform the claimed method because Biel teaches delivery of light to the oral cavity at various operating parameters which purportedly overlap with some parameters disclosed in the pending application.

Amended claim 1 recites a method in which requires that radiation be delivered from the phototherapy applicator in such a manner *so as to deposit a dose of radiation below an area of*



*facial skin*. The method further recites that *the area of tissue is irradiated so as to treat a dermatological or cosmetic condition in said area of the facial tissue*. Biel fails to disclose, teach, or suggest depositing a dose of radiation below an area of the facial skin so as to treat a dermatological or cosmetic condition in that area as required by amended claim 1.

Applicants note that the Biel application does not cure the deficiencies of the Biel patent. That is, the Biel application provides a method of photoeradication of cellular and acellular organisms including the steps of providing a surface active agent in association with a cellular or acellular organism, the surface active agent disorienting a membrane structure so that said membrane no longer functions as an effective osmotic barrier; providing a photosensitive material in association with the cellular or acellular organism; and applying light in association with the cellular or acellular organism to cause a disruption of the organism. The Biel application teaches that these methods can be utilized in in vitro and in vivo treatment protocols for infections, sterilization procedures, cancer cell eradication, virus and fungus eradication, spore eradication, and biofilm organism. See Abstract.

The Biel application does not disclose, teach, or suggest any method for providing a dermatological or cosmetic treatment, and certainly does not provide the method recited by amended claim 1. Accordingly, the Biel application fails to cure the deficiencies of the Biel patent. Thus, the Biel patent and/or the Biel application, alone or in any combination, do not disclose, teach, or suggest the method of independent claim 1. Therefore, Applicants respectfully request reconsideration and allowance of independent claim 1.

Claims 5, 6, 9, 15-17, and new claims 57-73 depend, directly or indirectly from independent claim 1, and are therefore allowable at least because they depend from an allowable base claim.

Independent Claim 97 and Dependent Claims 26, 28-30, 50-52, and 98-107

The Examiner rejects independent claim 20 and dependent claims 26, 28-30, and 50-52 as being obvious over the Biel patent in view of the Biel application. Applicants cancel independent claim 20 and present new independent claim 97 which incorporates the limitations

of original dependent claims 22 and 27, now canceled. Claims 26, 28-30, 50-52, and 98-107 all depend from new independent claim 97.

Independent claim 97 recites a method of treating a subject's blood. More specifically, the method includes exposing at least a portion of a subject's oral cavity to radiation having wavelength components in a range of about 280 nm to about 1800 nm to irradiate blood flowing in vasculature of the oral cavity and irradiating the oral cavity with said radiation during separate treatment sessions such that a radiation power in a range of about 1 mW to about 10 W is administered to the oral cavity during each treatment session. The method further recites irradiating the subject's oral cavity for a sufficiently long time so as to expose substantially an entire volume of the subject's blood to said radiation in one or more treatment sessions.

Regarding the step of *irradiating the subject's oral cavity for a sufficiently long time so as to expose substantially an entire volume of the subject's blood to said radiation in one or more treatment sessions*, the Examiner states that the Biel patent discloses this step because “[Regarding claims 27 and 52,] no specific manipulative steps for accomplishing such exposure are cited. Therefore, since Biel teaches the steps cited, the exposure would be accomplished.” Office Action, p. 5.

Biel does not teach, disclose, or suggest any method for treating blood. In rejecting original claim 20, the Office Action states that the use of the Biel device inherently provides some degree of biostimulation of some portion of blood flowing in this vasculature of the treatment area. New claim 97 recites *irradiating the subject's oral cavity for a sufficiently long time so as to expose substantially an entire volume of the subject's blood to said radiation in one or more treatment sessions*. One skilled in the art could determine the amount of time necessary to perform this step based on parameters specific to each subject (e.g., height, weight, etc.). The Biel patent fails to disclose any need or even desire to treat blood. Biel further fails to disclose any need or desire to treat blood with any length of irradiation exposure to achieve any volume of blood treatment. As such, Biel's method fails to directly or inherently disclose, teach, or suggest *irradiating the subject's oral cavity for a sufficiently long time so as to expose substantially an entire volume of the subject's blood to said radiation in one or more treatment*

*sessions*. Thus, Applicants respectfully request reconsideration and allowance of independent claim 97.

Claims 26, 28-30, 50-52, and 98-107 depend from new independent claim 97, and are therefore allowable at least because they depend from an allowable base claim.

Independent Claim 53 and Dependent Claims 54-56 and 74-77

Amended independent claim 53 provides a method of biostimulation via an oral cavity. The method includes irradiating at least a portion of tissue in an oral cavity with electromagnetic radiation having a power density equal to or greater than about  $1 \text{ W/cm}^2$  and at least one wavelength corresponding to an absorption band of an endogenous photoreactive substance located in the portion of tissue wherein the photoreactive substance absorbs sufficient electromagnetic radiation to cause the selected biostimulation effect.

In contrast to the claimed *power density equal to or greater than about  $1 \text{ W/cm}^2$* , the Biel patent teaches the use of a power density of about 0 to  $150 \text{ mW/cm}^2$  (see col. 1, lines 61-64). Thus, amended independent claim 53 clearly distinguishes the Biel patent.

The Biel application does not cure this deficiency because the Biel application likewise teaches a power density of about 0 to  $150 \text{ mW/cm}^2$  (see paragraphs [0008], [0010] – [0012], and [0049]). Therefore, the Biel patent and/or the Biel application, alone or in any combination, fail to teach, disclose, or suggest a method utilizing *a power density equal to or greater than about  $1 \text{ W/cm}^2$* .

In view of above, Applicants respectfully request reconsideration and allowance of independent claim 53. Claims 54-56 and 74-77 depend from claim 53, and are therefore allowable at least because they depend from an allowable base claim.

The Examiner also rejects dependent claim 19 pursuant to 35 U.S.C. § 103(a) as being unpatentable over the Biel patent in view of the Biel application, and further in view of U.S. Patent No. 6,135,774 of Hack et al. (“Hack”).

Claim 19 depends from independent claim 1. As detailed above, no combination of the Biel patent and the Biel application discloses, teaches, or suggests the method of amended claim 1. Hack fails to cure the deficiencies of the two Biel references in that Hack merely relates to the diagnosis and treatment of teeth. Therefore, Applicants respectfully request reconsideration and allowance of dependent claim 19 which is allowable at least because it depends from an allowable base claim.

The Examiner also rejects dependent claims 23 and 24 pursuant to 35 U.S.C. § 103(a) as being unpatentable over the Biel patent in view of the Biel application, and further in view of U.S. Patent No. 6,026,828 of Altshuler et al. ("Altshuler").

Claims 23 and 24 depend from new independent 97. As detailed above, no combination of the Biel patent and the Biel application disclose, teach, or suggest the method of new claim 97. Altshuler does not cure the deficiencies discussed above relating to the method of treating blood recited by claim 97. Therefore, Applicants respectfully request reconsideration and allowance of dependent claims 23 and 24 which are allowable at least because they depend from an allowable base claim.

### **CONCLUSION**

In summary, the above-identified patent application has been amended and reconsideration is respectfully requested for all the reasons set forth above. In the event that the amendments and remarks are not deemed to overcome the grounds for rejection, the Examiner is kindly requested to telephone the undersigned representative to discuss any remaining issues.

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Reply to final Office action of July 31, 2008

Group Art Unit: 3739  
Examiner: Henry M. Johnson III  
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Respectfully submitted,

By: / Reza Mollaaghababa /  
Reza Mollaaghababa  
Registration No. 43,810  
NUTTER MCCLENNEN & FISH LLP  
World Trade Center West  
155 Seaport Boulevard  
Boston, Massachusetts 02210-2604  
(617) 439-2000  
(617) 310-9000 (Fax)  
Attorney for Applicant

1782657.1